

Office Action Summary	Application No. 10/589,206	Applicant(s) BABICH ET AL.
	Examiner D. L. Jones	Art Unit 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-28 and 81-83 is/are pending in the application.
- 4a) Of the above claim(s) 82 and 83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 and 81 is/are rejected.
- 7) ☒ Claim(s) 27 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/11</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application
6) <input type="checkbox"/> Other: _____. |
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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 6/15/11 wherein claims 1-25, 29-80, and 84 were canceled and claims 26, 81, and 82 were amended.

Note: Claims 26-28 and 81-83 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to bis(heteroaryl) compounds and uses thereof as set forth in independent claims 26, 52, 56, 63, and 71.

WITHDRAWN CLAIMS

3. Claims 82-83 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENT

4. The Applicant's arguments and/or amendment filed 6/15/11 to the rejection of claims 26-28 and 81 made by the Examiner under 35 USC 102 and/or 112 have been fully considered and deemed persuasive for the following reasons. Therefore, the said rejections are hereby withdrawn.

112 First Paragraph Rejection

The 112 first paragraph rejection is WITHDRAWN because Applicant amended the claims to overcome the rejection.

112 Second Paragraph Rejections

The 112 second paragraph rejections are WITHDRAWN because Applicant amended the claims to overcome the rejection.

102 Rejection

In the office action mailed 3/21/11, the incorrect structure was referenced. The Examiner apologizes for the error. As a result, the 102 rejection is WITHDRAWN. However, the correct structure is referenced below in the new grounds of rejection.

CLARIFICATION OF THE RECORD

5. Applicant's election without traverse of Group I (claims 26-28 and 81) in the reply filed on 2/1/11 is once again acknowledged. Thus, the restriction requirement was deemed proper and made FINAL in the office action mailed 3/21/11.

In addition, the Examiner acknowledged Applicant's election of the species of Formula C wherein L = quinolinyl, R = (CH₂)₄CH(NH₂)(COOH); Z = COOH; m = 1; and n = 1. Initially, Applicant's elected species was searched. However, since no prior art was found to reject Applicant's elected species, the search has been expanded to that wherein L = quinolinyl; R = H; n = 1; m = 0; and Z = substituted 2-(carboxyl)heteroaryl group. The search was not further expanded because prior art was found which could be used to reject the claims.

NEW GROUNDS OF REJECTION

102 Rejection

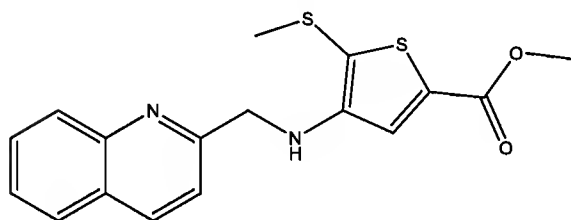
6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 26 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Illig et al (WO 00/47578).

Illig et al disclose heteroaryl amidines, methyl amidines, and guanidines that may be used as protease inhibitors (see entire document, especially, abstract). In particular, Illig et al disclose Example 224(a) which is directed to the formation of methyl-5-methylthio-4-[(2-quinolylmethyl)amino]thiophene-2-carboxylate (page 245, lines 4-12). The structure of Example 224(a) is



Methyl 5-methylthio-4-((2-quinolylmethyl)amino)thiophene-2-carboxylate

. Thus, both Applicant and Illig et al disclose a species encompassed by Applicant's Formula C wherein R = H; n = 1; m = 0; L = quinolyl; and Z = substituted 2-(carboxyl)heteroaryl group. Hence, the inventions disclose overlapping subject matter.

CLAIM OBJECTIONS

8. Claims 27 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Notes: It should be noted that prior art has not been cited against claims 27 and 28. In addition, it should be noted that the claims are only allowable as it relates to Applicant's elected species and the species of Illig et al cited in the rejection above. Specifically, the prior art neither anticipates nor renders obvious Applicant's

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radiolabeled elected species or the radiolabeling of the compound cited in the rejection of Illig et al above.

COMMENTS/NOTES

9. It should be noted that the full scope of the elected invention has not been searched because prior art was found which could be used to reject the claims.

10. Applicant's request for rejoining of the claims is noted. Once the pending product claim is indicated as allowable, the claims will be rejoined if both the allowable product and method claims are of the same scope.

11. The Illig et al (WO 00/47578) document is not being mailed with this office action. The document was previously mailed to Applicant on 3/21/11.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
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August 15, 2011